NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BAUSCH HEALTH IRELAND LIMITED, and SALIX PHARMACEUTICALS, INC. Plaintiffs, v. MYLAN LABORATORIES LTD., AGILA SPECIALTIES INC., MYLAN API US LLC, MYLAN INC., VIATRIS INC., and MYLAN PHARMACEUTICALS INC., Defendants.	Civil Action No. 21-10403 (SRC) (JSA) **OPINION**

CHESLER, District Judge

This matter comes before the Court on the motion to dismiss filed by Defendants Viatris Inc. ("Viatris"), Mylan Inc., Mylan API US LLC ("Mylan API"), Mylan Pharmaceuticals Inc. ("MPI"), Mylan Laboratories Ltd. ("MLL"), and Agila Specialties Inc. ("Agila," and collectively, "Defendants") as to the 16-count complaint filed against them by Plaintiffs Bausch Health Ireland Limited ("Bausch") and Salix Pharmaceuticals Inc. ("Salix," and collectively "Plaintiffs"). Plaintiffs oppose the motion and cross-move for jurisdictional and venue discovery. The Court has reviewed the papers submitted and proceeds to rule without oral argument, pursuant to Federal Rule of Civil Procedure 78. For the reasons that follow, Defendants' motion will be granted in part and Plaintiffs' cross-motion will be denied. The action further will be transferred to the Northern District of West Virginia.

I. Background

Under the Hatch-Waxman Act, to market a new drug, a sponsor submits to the Food and Drug Administration ("FDA") a new drug application ("NDA"). *See Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 404 (2012). An NDA must contain the drug's proposed labeling and directions for use and extensive information on clinical trials showing that the drug is safe and effective for its labeled use. *See id.* Brand-drug sponsors are also required to inform the FDA of all its patents covering the drug or its labeled methods of use. *See* 21 U.S.C. § 355(b)(1), (c)(2). These patents are publicly listed in what is known as the Orange Book. *Caraco*, 566 U.S. at 405–06. The Hatch-Waxman Act also includes an option for generic-drug sponsors to submit an abbreviated new drug application ("ANDA"). Using an ANDA, a generic-drug sponsor need not repeat a brand drug's safety-and-efficacy trials at substantial expense. Instead, a generic-drug sponsor must show that its product is bioequivalent to the reference brand drug. *See id.* If so, the sponsor can market that generic drug with a label matching that of the brand drug. *See id.* at 415, 425.

An ANDA applicant that believes a brand-sponsor's patent is invalid, unenforceable, or not infringed can ask for full approval during the patent's term and include with its ANDA a paragraph IV certification. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV).[1] Submitting an ANDA that seeks approval to market a drug while that drug is on-patent is patent infringement. 35 U.S.C. § 271(e)(2); *see also Valeant Pharms. N. Am. LLC v. Mylan Pharms. Inc.*, 978 F.3d 1374, 1381–82 (Fed. Cir. 2020).[1] The generic sponsor must provide a so-called paragraph IV notice to the

[1] An ANDA applicant might choose to avoid infringing upon the original drug's patent by waiting out the patent's term. If so, the applicant includes with its ANDA a so-called paragraph III certification for that patent. See 21 U.S.C. § 355(j)(2)(A)(vii)(III).

patentee brand-drug sponsor after it submits its ANDA and the FDA confirms receipt of the submission. *See* 21 U.S.C. § 355(j)(2)(B); *see also id.* § 355(j)(2)(B)(ii)(I). A brand-drug sponsor that sues within 45 days of receiving notice of a generic's paragraph IV certification is entitled to an automatic thirty-month stay of FDA approval so the infringement and validity questions can be worked out in court. 21 U.S.C. § 355(j)(5)(B)(iii); *Actavis*, 570 U.S. at 143, 133 S.Ct. 2223.

The instant litigation concerns Defendants' alleged filing of ANDA No. 215686 to market generic versions of Plaintiff Salix's plecanatide oral tablets product, Trulance. (Compl. ¶¶ 47–48.) Salix holds an approved NDA for Trulance, and the patents-in-suit are listed in the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" publication (the "Orange Book"). (*Id.* ¶¶ 9, 45 (including United States Patents Nos. 7,041,786 ("the '786 patent"), 7,799,897 ("the '897 patent"), 8,637,451 ("the '451 patent"), 9,610,321 ("the '321 patent"), 9,616,097 ("the '097 patent"), 9,919,024 ("the '024 patent"), 9,925,231 ("the '231 patent") and 10,011,637 ("the '637 patent").)

As part of the ANDA process, Defendants allegedly submitted a paragraph IV certification as to six of the eight patents-in-suit and a paragraph III certification as to the remaining two. (*Id.* ¶¶ 47; *see also* Meckstroth Decl., Ex. C.)[2] Following the submission of these certifications and the FDA's acknowledgment of the same, MPI sent Salix, Bausch, and non-party Synergy Pharmaceuticals Inc. a notice-of-certification letter, dated March 18, 2021, which, among other things, notified Plaintiffs of Defendants' intentions to seek the FDA's approval to market certain of their proposed products prior to the expiration of the patents-in-suit. (*See* Compl. ¶¶ 49, 51–54; Meckstroth Decl., Ex. D.)

[2] The Third Circuit has held that a district court may consider documents "integral to or explicitly relied upon in the complaint." *In re NAHC, Inc. Sec. Litig.*, 306 F.3d 1314, 1331 (3d Cir. 2002) (quoting *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997)).

On April 28, 2021, Plaintiffs filed the 16-count Complaint against Defendants. For each of the eight patents upon which Defendants allegedly infringe, Plaintiffs pursue both a claim of infringement under the United States patent laws, 35 U.S.C. § 271(e)(2), and a claim under the Declaratory Judgment Act, 28 USC §§ 2201 and 2202. (*Id.* ¶¶ 55–142.)[3]

II. Discussion

Defendants move to dismiss the complaint on numerous grounds. *First*, Defendants assert that the District of New Jersey is an improper venue under 28 U.S.C. § 1400(b) as to Mylan Inc., Mylan API, MPI, or Viatris. *Second*, Defendants contend that Plaintiffs have failed to state a claim against MLL, Agila, Mylan API, Mylan Inc., and Viatris with respect to the Infringement Counts. *Third*, Defendants argue that Plaintiffs fail to state a claim and that this Court lacks subject matter jurisdiction with respect to the Declaratory Judgment Counts. *Fourth*, Defendants claim that the Court lacks personal jurisdiction over MLL. In turn, Plaintiffs cross-move for jurisdictional and venue discovery.

A. Defendants' Motion to Dismiss for Improper Venue as to Mylan Inc., Mylan API, MPI, and Viatris and Plaintiffs' Cross-Motion for Venue and Jurisdictional Discovery.[4]

28 U.S.C. § 1400(b) provides that a patent infringement case may be brought in the judicial

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[3] In their opposition to Defendants' motion, Plaintiffs request that the Court dismiss without prejudice Counts III, IV, V and VI, since these counts concern patents for which MPI submitted to the FDA a III certification, thus indicating that MPI did not seek to enter the market until after the patents have expired. (Opp. at 25 n.9.) The Court will grant that request. Of the remaining causes of action, Counts I, VII, IX, XI, XIII, and XV assert claims of patent infringement against Defendants (the "Infringement Counts") while Counts II, VIII, X, XII, XIV, and XVI assert claims pursuant to the Declaratory Judgment Act (the "Declaratory Judgment Counts").

[4] Defendants do not dispute that venue is proper in this district for Agila as a resident of New Jersey, *see* 28 U.S.C. § 1400(b), or for MLL as a foreign entity. *See In re HTC Corp.*, 889 F.3d 1349, 1360 (Fed. Cir. 2018); *see also* 28 U.S.C. § 1391(c)(3).

district where (1) "the defendant resides," or (2) the defendant "has committed acts of infringement and has a regular and established place of business."[5] Section 1400(b) is the "sole and exclusive provision controlling venue in patent infringement actions," *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514, 1519 (2017), and "is intended to be restrictive of venue in patent cases compared with the broad general venue provision," *In re ZTE (USA) Inc.*, 890 F.3d 1008, 1014 (Fed. Cir. 2018).[6] Venue may be imputed to a corporate defendant under an alter ego or veil piercing theory in a patent infringement action, but where related companies have maintained corporate separateness, the place of business of one corporation is not imputed to the other for venue purposes. *Celgene Corp. v. Mylan Pharms. Inc.*, 17 F.4th 1111 (Fed. Cir. 2021).

1. Standard of Review

Plaintiffs bear the burden of establishing that venue in this district is proper. *In re ZTE (USA) Inc.*, 890 at 1013. As a general rule, "[t]he Court will accept any venue-related allegations in the complaint as true, unless they are contradicted by the defendant's evidence." *Novartis Pharm. Corp. v. Accord Healthcare Inc.*, 2019 WL 2502535, at *2 (D. Del. June 17, 2019) (citing *Bockman v. First Am. Mktg. Corp.*, 459 F. App'x 157, 158 n.1 (3d Cir. 2012)). In addition to the venue-related allegations found in the Complaint, the Parties have submitted declarations and documentary evidence in support of their respective positions. Since this Court has the benefit of a factual record, the Court will consider the evidence to determine whether venue is proper. *See In re Cray Inc.*, 871 F.3d 1355, 1364 (Fed. Cir. 2017) (evaluating the various venue facts submitted

[5] Defendants contend that neither Mylan Inc., Viatris, Mylan API, nor MPI "reside" in New Jersey and Plaintiffs do not argue otherwise. (Mot. at 13.) Accordingly, only the second prong of the Section 1400(b) venue analysis is at issue here.

[6] Plaintiffs also assert in the Complaint that venue is proper under the general venue statute, 28 U.S.C. § 1391, considering their claims for declaratory relief. Since these claims will be dismissed, *see infra* Section II.C, Plaintiffs cannot avail themselves of this venue provision.

without discussing whether they had been plead in the operative complaint); *Bristol-Myers Squibb Co. v. Aurobindo Pharma USA Inc.*, 2018 WL 5109836, at *2 (D. Del. Oct. 18, 2018) (considering evidence outside of the complaint on a renewed motion to dismiss pursuant to Rule 12(b)(3)). When deciding a motion to dismiss for improper venue, a court draws all reasonable inferences and resolves factual conflicts in a plaintiff's favor. *High 5 Games, LLC v. Marks*, 2019 WL 3761114, at *13 (D.N.J. Aug. 9, 2019) (citing *Bockman*, 459 F. App'x at 158 n.1). Because the record before the Court is limited to affidavits and other written materials, Plaintiffs are obliged only to make a *prima facie* showing that venue is appropriate. *Cf. Celgard, LLC v. SK Innovation Co.*, 792 F.3d 1373, 1378 (Fed. Cir. 2015) (requiring *prima facie* showing when determining personal jurisdiction after jurisdictional discovery but without the benefit of a jurisdictional hearing); *see also Gulf Ins. Co. v. Glasbrenner*, 417 F.3d 353, 355 (2d Cir. 2005) (quoting *CutCo Industries, Inc. v. Naughton*, 806 F.2d 361, 364–365 (2d Cir. 1986) ("If the court chooses to rely on pleadings and affidavits, the plaintiff need only make a *prima facie* showing of [venue]") (alterations in original)).

2. *Only MPI has committed an alleged act of infringement and did not do so in New Jersey.*

Under the Hatch-Waxman Act:

> It shall be an act of infringement to submit (A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(2). "[I]t is the submission of the ANDA, and only the submission, that constitutes an act of infringement in this context." *Valeant*, 978 F.3d at 1384. While the Federal Circuit in *Valeant* declined to "define what all relevant acts involved in the preparation and

submission of an ANDA might be," *id.* at 1383 n.8, it has since emphasized that "the relevant infringing acts must, at a minimum, fairly be *part of* the submission—not merely 'related to' it in some broader sense." *Celgene*, 17 F.4th at 1121.

Defendants contend that MPI alone prepared and electronically submitted the ANDA, and that it did so in West Virginia and sent the ANDA to the FDA in Maryland. (Mot. at 13–14; Declaration of Keith Meckstroth ("Meckstroth Decl.") at ¶ 35.) Defendants argue that Mylan Inc., Agila, Mylan API, MLL, and Viatris had no role in the development or preparation of the ANDA. (Mot. at 13–14.) Plaintiffs counter, *inter alia*, that Defendants are collectively involved in and will financially benefit from Mylan API's New Jersey manufacture of plecanatide active ingredient for formulation in tablets related to the infringing ANDA No. 215686, and that Defendants accordingly have engaged in actions in New Jersey rendering them ANDA "submit[ters]" within the meaning of 35 U.S.C. § 271(e). (Opp. at 7–12.)

a. Defendants' corporate separateness is presumed and the Court will not disregard their corporate forms.

Under the Third Circuit's alter ego doctrine, courts will disregard the corporate form to "prevent fraud, illegality, or injustice," "when recognition of the corporate entity would defeat public policy or shield someone from liability for a crime," or "when the parent so dominated the subsidiary that it had no separate existence." *Pearson v. Component Tech. Corp.*, 247 F.3d 471, 484 & n.2 (3d Cir. 2001).[7] Among other possible considerations, courts must consider "gross undercapitalization, failure to observe corporate formalities, nonpayment of dividends, insolvency of the [subsidiary] corporation, siphoning of funds from the [subsidiary] corporation by

[7] Plaintiffs must also satisfy the heightened pleading requirement of Fed. R. Civ. P. 9(b) to pierce the corporate veil or establish alter ego relationships between Defendants. *See Board of Trustees of Teamsters Local 863 Pension Fund v. Foodtown, Inc.*, 296 F.3d 164, 172 n.10 (3d Cir. 2002).

the dominant stockholder, nonfunctioning of officers and directors, absence of corporate records, and whether the corporation is merely a facade for the operations of the dominant stockholder." *Id.*, 247 F.3d at 484–85 & n.2. This inquiry is meant to determine whether the entities' separateness "is little more than a legal fiction"—a "notoriously difficult" burden. *Id.*, 247 F.3d at 485 ("Plaintiffs must essentially demonstrate that in all aspects of the business, the two corporations actually functioned as a single entity."). A court "consider[s] whether veil piercing is appropriate in light of the totality of the circumstances." *Trinity Indus., Inc. v. Greenlease Holding Co.*, 903 F.3d 333, 365 (3d Cir. 2018).[8]

Here, Plaintiffs have not pled facts to support the conclusion that Defendants are mere alter egos of the others, and there are no allegations of (or evidentiary support establishing) fraud or injustice that would permit Plaintiffs to pierce the corporate veil for any of the Defendants. Instead, Plaintiffs identify several factors which purportedly evidence Defendants' singular identity within Viatris, including:

- Viatris' use of an online product catalogue on Viatris.com that does not "differentiate between subsidiaries as to the ANDA or NDA holder for each product."
- Viatris' use of one hiring page, one newsroom for press releases, one customer-service email address, one Twitter page, one YouTube channel, and one LinkedIn page.
- Viatris' reporting of consolidated financial and operation status of "Viatris Inc. and Subsidiaries."
- Viatris' use of its trademarked logos—Viatris, Global Healthcare Gateway®, and Partner of Choice—across its products and branding.

[8] Predominately relying on *Minnesota Min. & Mfg. Co. v. Eco Chem, Inc.*, 757 F.2d 12567 (Fed. Cir. 1985), Plaintiffs argue that the Court need not find that Viatris-related entities are alter egos to impute a given defendant's "regular and established place of business" to another. However, the Federal Circuit in *Minnesota Mining* clearly indicated that its decision involved an alter ego analysis, and recently reiterated in *Celgene* that "[v]enue may be imputed under an alter-ego or veil-piercing theory." *Celgene*, 17 F.4th at 1125 (citing *Minn. Mining*, 757 F.2d at 1265).

- The contact persons for the various entities identified within the ANDA all use an email domain of @viatris.com.

- The preparation and submission of ANDA No. 215686 involved Viatris in-house counsel.[9]

- That Viatris entities "coordinate their regulatory communications with the FDA to further one another's submissions."[10]

(Opp. at 5–6, 11–12 (citing Declaration of William Deni ("Deni Decl.") Exs. 6–15, 22, 24–26, 31–33).) These allegations "[a]t most . . . show[] collaboration, not commonality." *Celgene*, 17 F.4th at 1126; *see also Pearson*, 247 F.3d at 485 ("[C]ourts have refused to pierce the veil even when subsidiary corporations use the trade name of the parent, accept administrative support from the parent, and have a significant economic relationship with the parent."); *Mills v. Ethicon, Inc.*, 406 F. Supp. 3d 363, 385 (D.N.J. 2019) ("[T]he fact that the parent and subsidiary share the same 'brand' is insufficient."); *Laverty v. Cox Enters.*, 2019 WL 351905, at *4 (D.N.J. Jan. 29, 2019) (holding that subsidiary was not alter ego of parent company where plaintiff relied "on general corporate and marketing statements that vaguely touch on the relationship" between parent and subsidiary). Accordingly, the Court will not disregard Defendants' corporate forms.

[9] Namely, Defendants' in-house Patent Litigation Counsel, who holds himself out on LinkedIn as a "Viatris" employee, emailed Plaintiffs' counsel "on behalf of MPI" shortly after the ANDA was submitted. (Opp. at 11 (citing Deni Decl. Ex. 32).) Furthermore, the ANDA identifies as a "Regulatory Contact" another individual who publicly acknowledges that she is employed at "Viatris Pharmaceuticals." (*Id*. at 11–12 (citing Deni Decl. Ex. 22).)

[10] As support, Plaintiffs offer evidence demonstrating that: (i) MLL appointed MPI as a U.S. agent for DMF No. 34227; (ii) MLL paid the user fees in association with the DMF; and (iii) MLL directly communicated with the FDA New Jersey Division regarding certain manufacturing facility inspections. (Opp. at 9 (citing Deni Decl. Exs. 24–26).)

b. Neither Mylan Inc., Mylan API, nor Viatris individually suffices as a "submitter" of ANDA No. 215686.

Plaintiffs have not demonstrated that Mylan Inc., Mylan API, or Viatris have acted in a manner as to give rise to considering them a submitter. Beyond the collective entity allegations and evidence, described *supra*, between these three Defendants Plaintiffs make particularized arguments only as to Mylan API. Plaintiffs argue that Mylan API's New Jersey manufacture of plecanatide active ingredient renders it an ANDA submitter pursuant to 35 U.S.C. § 271(e). (Opp. at 8.) According to Plaintiffs, this evidences that Mylan API "intends to benefit directly if the ANDA is approved by participating in the manufacture, importation, distribution and/or sale of the generic drug [i]s subject to suit under § 271(e)." (*Id.*)[11]

However, it is not sufficient under the Hatch-Waxman Act that an entity intends to and will benefit from the approval of an ANDA—an entity must also "participate in the preparation of the ANDA." *Otsuka Pharm. Co. v. Hetero USA, Inc.*, 2020 WL 6822971, at *2 (D. Del. Nov. 20, 2020); *In re Rosuvastatin*, 703 F.3d 511, 528 (Fed. Cir. 2012) (finding infringement sufficiently alleged where party intended to benefit directly if the ANDA was approved *and* signed the ANDA as the agent of its foreign parent-applicant). Plaintiffs do not explain "*how*" Mylan API is involved in the ANDA process—allegations of Mylan API's purported manufacture of the plecanatide active ingredient are simply insufficient to demonstrate the entity's active participation in the preparation of the ANDA. *Cf. Celgene*, 17 F.4th at 1129; *see also Valeant*, 978 F.3d at 1381 ("A

[11] Defendants vigorously contest Plaintiffs' assertion that Mylan API will be involved in the manufacture of plecanatide API in connection with ANDA No. 215686 and the Parties have submitted evidence in support of their respective positions. (Reply at 3–5; *see also* ECF No. 44) The Court need not dive into dispute: Even accepting Plaintiffs' version of the facts (an approach which is perhaps more favorable to Plaintiffs than merely construing the record in their favor), they have still failed to make a *prima facie* showing that Mylan API could be considered an ANDA submitter pursuant to 35 U.S.C. § 271(e).

plain language reading of this provision directs us to the conclusion that it is the submission of the ANDA, and only the submission, that constitutes an act of infringement in this context."); *Adverio Pharma GmbH v. Alembic Pharms. Ltd.*, 2019 WL 581618, at *3 n.4 (D.N.J. Mar. 12, 2020) ("[C]ourts [have] held that third-party manufacturers of the active ingredient for proposed ANDA products, who were uninvolved in the submission of the ANDA, were *not* 'submitters' within the meaning of the statute."). Because Plaintiffs have not demonstrated that Mylan API participated in preparing ANDA No. 215686, they have not established that it is a "submitter" under § 271(e)(2).[12]

c. Plaintiffs have not alleged facts sufficient to make a *prima facie* showing that MPI committed an act of infringement in New Jersey.

Plaintiffs' attempts to tie MPI's alleged infringement to New Jersey rely on the actions of other Defendants. Those actions can neither be imputed to MPI, nor would they be sufficient even if they could. *Supra* Sections II.A.2.a–b. Because Plaintiffs do not make any particularized allegation or showing that MPI took any acts in New Jersey that can fairly be considered "part of the [ANDA] submission," venue is not proper as to MPI. *Celgene*, 17 F.4th at 1121.

3. Neither Mylan Inc., MPI, nor Viatris have "regular and established places of business" within the District of New Jersey.[13]

Even if Plaintiffs demonstrated that Mylan Inc., MPI, or Viatris have committed acts of

[12] The Parties skirmish over whether the supply of plecanatide API by Mylan API (or, as later discussed, MLL) is an activity "protected by the safe harbor of § 271(e)(1)." *Shire LLC v. Amneal Pharmaceuticals, LLC*, 802 F.3d 1301, 1309–10 (Fed. Cir. 2015). The Court declines to take a position on this question because, whether the safe harbor applies or not, Plaintiffs have not demonstrated that Mylan API participated in preparing ANDA No. 215686.

[13] Defendants concede that Mylan API meets this element of the venue statute. Because, as just discussed, Mylan API has not "committed acts of infringement" in the District, venue remains improper as to the defendant.

infringement in the District, Plaintiffs have failed to establish that these Defendants have "regular and established places of business" here. There are three factors relevant to this element of a patent venue inquiry: "(1) there must be a physical place in the district; (2) it must be a regular and established place of business; and (3) it must be the place of the defendant." *Cray*, 871 F.3d at 1360.

Plaintiffs assert numerous grounds by which this Court should find that Defendants meet these criteria for venue in the District: (i) the existence of brick and mortar offices by certain Defendants and other entities; (ii) the residence of Defendants' employees; (iii) the operation of Defendants' clinical trials here; (iv) Defendants' New Jersey business registrations; (v) Defendants' revenues and payments within the state; and (vi) Defendants' litigation activities here. None of these grounds, individually or collectively, are sufficient to bring about venue within this District.

Brick and Mortar Offices. Plaintiffs identify four "brick and mortar offices" in support of their argument for venue in the District. (Opp. at 17.) Of these locations, only one concerns a relevant Defendant—Mylan Inc.[14] With respect to the address identified by Plaintiffs and attributed to Mylan Inc., Defendants aver that "Mylan Inc. has never operated out of this location", "[i]n 2018, Mylan Inc. executed an agreement to sublease the entirety of the [property] to an independent, third-party organization," and "[n]o Mylan Inc. employee has ever been assigned to or worked from the [property]." (Meckstroth Decl. ¶ 61.) Even construing the facts in Plaintiffs' favor, the mere existence of this property, from which no Mylan Inc. employee has worked from,

[14] Plaintiffs also identify addresses associated to, variously, Mylan API and non-Parties Mylan Specialty L.P. and Greenstone LLC. Because Mylan API does not contest that it has a regular and established place of business in the District, and Plaintiffs do not (make any attempt to) demonstrate that the two non-Parties are alter egos of any Defendant, these addresses are irrelevant to the inquiry.

is insufficient to establish venue in the District. *In re Google LLC*, 949 F.3d 1338, 1345 (Fed. Cir. 2020) (venue requires "the regular, physical presence of an employee or other agent of the defendant conducting the defendant's business at the alleged 'place of business'").

New Jersey-Based Employees. Plaintiffs assert that the New Jersey residence of certain of Defendants' employees establishes that Defendants have "regular and established places of business" in the District. However, the inquiry concerns the place "*of the defendant*, not solely a place of the defendant's employee." *Cray*, 871 F.3d at 1363. Defendants state that, as of the date of the Complaint, MPI had three (out of 2,285) employees residing in New Jersey, while Mylan Inc. had 11 (out of 785) employees residing in the state. (Meckstroth Decl. ¶¶ 19, 63.) Defendants further offer evidence which belies the suggestion that either MPI or Mylan Inc. have "ratified" New Jersey as its place of business.[15] *Cray*, 871 F.3d at 1362–63.

Plaintiffs also complain that Defendants in the Meckstroth Declaration fail to provide employment information concerning other Defendants, notably Mylan API and Viatris. Defendants concede that Mylan API has a regular and established place of business in the District, and information regarding its employees have no bearing on whether other Defendants have regular and established places of business in the District. With respect to Viatris, Defendants have

[15] Specifically, the Meckstroth Decl. avers that neither MPI nor Mylan Inc.: "leases or owns any portion of those employees' homes or has exercised any other type of possession or control over those employees' homes at any time; contributes to any costs to purchase or maintain the employees' homes; played any part in the selection of those employees' personal residence in New Jersey; conditioned employment on any employee's continued residence in New Jersey or the storing of any products or materials at any employee's residence in New Jersey to be sold in or from New Jersey; lists any employee's home address in business or telephone directories of Mylan Inc. or any Viatris affiliate; requires employees to [store] Mylan Inc.-related materials and samples in their homes in New Jersey; requires employees to rent storage lockers to store Mylan Inc.-related materials and samples in New Jersey; offered or provides any secretarial or administrative support at any employee's home in New Jersey; or holds out any employee's personal residence at the company's place of business." (Meckstroth Decl. ¶¶ 19, 63.)

submitted evidence attesting that Viatris does not have employees in New Jersey or elsewhere. (Supp. Meckstroth Decl. ¶ 8.)[16]

Clinical Trials. Plaintiffs explain that Mylan Inc. and MPI regularly conduct clinical trials in locations throughout New Jersey, including clinical trials that are "sponsored" by certain Defendants in "collaboration with" other entities.[17] (Opp. at 18.) However, Plaintiffs have not submitted evidence, let alone alleged, that MPI, Mylan Inc., or Viatris: (i) owns or leases any of the clinical trials' locations; (ii) employed the personnel used to run the clinical trials; (iii) are identified by name on the building where the clinical trials are run; or (iv) identify the address of the clinical trial as a place of business. Clinical trials conducted by third parties—which may be sponsored by or in collaboration with one or more Defendants or their affiliates—do not amount to a physical place of business. *See, e.g.*, *Regents of Univ. of Minn. v. Gilead Scis., Inc.*, 299 F. Supp. 3d 1034, 1044 (D. Minn. 2017) (defendant's "'control' over dozens of clinical trials in Minnesota" was insufficient to demonstrate a "place of the defendant").

Business Registrations. MPI, Mylan Inc., and Viatris (along with Mylan API) are all registered with the New Jersey Department of Health, and hold manufacturer, wholesaler, or manufacturer and wholesaler licenses. (Opp. at 19 (citing *Otsuka Pharm. Co.*, 106 F. Supp. 3d at 460 (stating that Mylan Inc, MPI and MLL hold a wholesale distribution license in New Jersey);

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[16] Following briefing on Defendants' motion, Plaintiffs submitted a letter claiming that this assertion in the Meckstroth Declaration is "flatly contradicted by public information." (ECF No. 44 at 2.) A cursory review of the evidence which Plaintiffs proffer (which include filings with the U.S. Securities and Exchange Commission and a publicly available report issued by Defendants) reveals that descriptions concerning the size of the "Viatris" workforce in these documents include in their number Viatris, Inc. and its subsidiaries. *E.g.*, www.sec.gov/Archives/edgar/data/0001792044/000179204421000009/vtrs-20201231.htm.

[17] Plaintiffs identify at least one clinical trial conducted in New Jersey which was "sponsored" by Mylan Inc. and "collaborated" with MPI, while another trial was "sponsored" by "Upjohn US 1 LLC," a (non-Party) subsidiary of Viatris, in collaboration with "Mylan Inc." (Opp. at 18 (citing Deni Decl. Exs. 43–45).)

Meckstroth Decl. at ¶ 18).) According to Plaintiffs this, in conjunction with Defendants' boasts to "leverage a broad network of local and global access channels" and partner with local entities to conduct clinical trial locations discussed above, demonstrate that Defendants' places of business in New Jersey are "regular and established." (*Id*. (quoting Deni Decl., Ex. 46).) However, simply *doing* business in a district or being *registered* to do business in a district is insufficient, without more, to make that district a regular and established place of business. *Bristol-Myers Squibb Co. v. Mylan Pharm. Inc.*, 2017 WL 3980155, at *16 (D. Del. Sept. 11, 2017), *disagreed with on other grounds*, *Valeant*, 978 F.3d 1374 (Fed. Cir. 2020)

New Jersey-Related Payments and Revenues. Plaintiffs contend that, from 2013–2019, MPI and (non-Party) Mylan Specialty L.P. made more than 700 and 9,500 payments, respectively, to physicians or teaching hospitals in New Jersey, collectively totaling over $888,000. (Opp. at 19 (citing Deni Decl., Exs. 47–48).) Defendants also purportedly derive substantial revenue from New Jersey. *See Otsuka Pharm.*, 106 F. Supp. 3d at 460 (noting that in New Jersey, Mylan Inc. and MPI "generate[] annual revenues in excess of" $100 million and $50 million, respectively).[18] However, doing business in a state does not establish venue. *See Symbology Innovations, LLC v. Lego Sys., Inc*., 282 F. Supp. 3d 916, 931 (E.D. Va. 2017) ("Revenue derived from the forum has no bearing on whether § 1400(b)'s requirements are met.").

Litigation Activities. Plaintiffs contend that Defendants have "regular and established" places of business in New Jersey because Defendants "regularly litigate patent infringement cases and other cases in this Court," as evidenced by their appearances in over 100 cases in this District

[18] Plaintiffs also direct the Court's attention to a 2018 advertisement which represented that "Mylan generics saved New Jersey ~$490 million." (Opp. at 19 (citing Deni Decl. Ex. 49.) This metric does not tend to show a "place" of business and does not weigh in Plaintiffs' favor.

since 2000. (Opp. at 19.) The Court is unpersuaded by such a novel (yet entirely unconvincing) argument.

4. Plaintiffs' Cross-Motion for Venue and Jurisdictional Discovery is Denied.

The Supreme Court has advised that "where issues arise as to jurisdiction or venue, discovery is available to ascertain the facts bearing on such issues." *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 351 n. 13 (1978). In general, courts within the Third Circuit permit jurisdictional discovery "unless the plaintiff's claim is 'clearly frivolous.'" *Toys "R" Us, Inc. v. Step Two, S.A.*, 318 F.3d 446, 456 (3d Cir. 2003) (quoting *Massachusetts Sch. of Law at Andover, Inc. v. Am. Bar Ass'n*, 107 F.3d 1026, 1042 (3d Cir. 1997)). Nonetheless, jurisdictional discovery is not warranted unless the plaintiff "presents factual allegations that suggest 'with reasonable particularity' the possible existence of the requisite 'contacts between [the party] and the forum state . . . .'" *Id.* (quoting *Mellon Bank (E.) PSFS, Nat. Ass'n v. Farino*, 960 F.2d 1217, 1223 (3d Cir. 1992)). A plaintiff may not "undertake a fishing expedition based only upon bare allegations, under the guise of jurisdictional discovery." *Eurofins Pharma US Holdings v. BioAlliance Pharma SA*, 623 F.3d 147, 157 (3d Cir. 2010); *see Lincoln Ben. Life Co. v. AEI Life, LLC*, 800 F.3d 99, 108 n. 38 (3d Cir. 2015) ("[J]urisdictional discovery is not available merely because the plaintiff requests it.").

Notwithstanding the Third Circuit's liberal standard, Plaintiffs have not presented factual allegations sufficient to find that discovery is warranted. While Plaintiffs tout the supposed abundance of Defendants' contacts with the District, their requests[19] are futile and unsupported by

[19] Plaintiffs in their briefing seek discovery regarding: (i) Mylan API's participation in the research, development, manufacture and/or formulation of plecanatide; (ii) Defendants' involvement in any research, development, manufacture and/or formulation of plecanatide and/or Defendants' proposed ANDA product; (iii) Defendants' preparation and submission of ANDA No. 215686 and DMF No. 34227 to the FDA; (iv) Defendants' coordination of their regulatory communications with the FDA to further the submission

specific allegations or submitted evidence. *Symbology*, 282 F. Supp. 3d at 934 (denying a request for venue-related discovery because "[Plaintiff] fails to identify any source of information or fact that would change the Court's analysis of whether [Defendant] has a regular and established place of business in this District."); *Barth v. Walt Disney Parks & Resorts U.S., Inc.*, 697 F. App'x 119, 120 (3d Cir. 2017) (affirming denial of request for jurisdictional discovery, where "jurisdictional discovery would have been futile."). To the extent that Plaintiffs' requests may seek information that could meaningfully establish that Defendants (other than MPI) committed some act of patent infringement—such as their request for discovery concerning "Defendants' preparation and submission of ANDA No. 215686"—they have failed to allege with particularity facts demonstrating that: (i) Mylan Inc., Mylan API, or Viatris committed "relevant infringing acts" that are "fairly be part of the submission" and "not merely 'related to' it in some broader sense," or (ii) MPI committed acts of infringement within the District of New Jersey by dint of an alter ego theory. *Celgene*, 17 F.4th at 1121; *see also Galderma Labs, L.P. v. Medinter U.S., LLC et al.*, No. 18-cv-1892, Dkt. No. 98 at 11-14 (D. Del. Oct. 25, 2019) (denying discovery where "Plaintiffs have failed to point to any record evidence relating to most of the factors that the Third Circuit has used to address corporate separateness"; "what little evidence Plaintiffs have put forward does not speak impactfully to the prospect that Anteco's corporate separateness from Attwill is a 'legal fiction'"). Discovery on these issues would amount to a futile, costly, and unwarranted fishing

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of ANDA No. 215686; (v) Defendants' expected benefits from ANDA No. 215686, if approved; (vi) the corporate relationship among all Defendants; (vii) Defendants' internal operations, such as capitalization, legal and accounting operations, cross-company payments, officers and directors; (viii) Defendants' employees or independent contractors that reside or are present in New Jersey; (ix) Defendants' contracts with New Jersey-based entities; (x) Defendants' property ownership in New Jersey; and (xi) Defendants' other New Jersey footprint and other specific details addressed herein. (Opp. at 33–34.)

expedition.[20]

B. Motion to Dismiss the Infringement Counts for Failure to State a Claim Against MLL and Agila.[21]

A complaint will survive a motion under Rule 12(b)(6) only if it states "sufficient factual allegations, accepted as true, to 'state a claim for relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic v. Twombly*, 550 U.S. 544, 570 (2007)). A complaint states a plausible claim if it "pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556). While the complaint need not demonstrate that a defendant is probably liable for the wrongdoing, allegations that give rise to the mere possibility of unlawful conduct will not do. *Iqbal*, 556 U.S. at 678; *Twombly*, 550 U.S. at 557. Furthermore, a court will "disregard rote recitals of the elements of a cause of action, legal conclusions, and mere conclusory statements." *James v. City of Wilkes-Barre*, 700 F.3d 675, 679 (3d Cir. 2012).

Limiting its consideration of the question to the allegations in the Complaint, the Court is unable to find *any* individualized allegation supporting the conclusion that MLL or Agila constitute "submitters" of ANDA No. 215686. Instead, the Complaint, in conclusory fashion, alleges that "*Defendants*" "filed or caused to be filed with the FDA ANDA No. 215686" and "acted in concert to prepare and submit Defendants' ANDA No. 215686 and [the March 18, 2021 notice-of-

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[20] The Court is aware of a recently authored opinion in which Judge Leonard Stark found that venue-related discovery was warranted concerning various businesses that were affiliated with an ANDA filer, notwithstanding that these other businesses did not themselves file the ANDA. *Novartis Pharms. Corp. v. Handa Neuroscience, LLC*, C.A. No. 21-645-LPS (D. Del. Mar. 1, 2022). The Court is not persuaded that the facts present in *Novartis* are sufficiently similar to those here, as they relate to certain Defendants' purported participation in MPI's submission of the ANDA, and the requested discovery is not merited.

[21] Defendants also seek dismissal of the claims against Mylan Inc., Mylan API, and Viatris on Rule 12(b)(6) grounds. Because venue in this district is improper as to these defendants, this Court declines to adjudicate that component of their motion. *See Alpine Bus. Grp., Inc. v. Sabathia*, No. 10-4850, 2011 WL 589959, at *2 (D.N.J. Feb. 10, 2011).

certification letter to Plaintiffs]." (Complaint ¶¶ 47, 50 (emphasis added).). That is not enough, and Plaintiffs fail to demonstrate "*how* [each Defendant] is involved in the ANDA process." *Celgene*, 17 F.4th at 1129 (finding insufficient conclusory allegations that defendants "work in concert with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products" and collectively "filed [the] ANDA" at issue). Even when construing the Complaint in the light most favorable to Plaintiffs, they have failed to allege that either MLL or Agila are liable for infringement under the Hatch-Waxman Act.[22]

If a complaint is vulnerable to 12(b)(6) dismissal, the district court must permit a curative amendment, unless an amendment would be inequitable or futile. *Alston v. Parker,* 363 F.3d 229, 235 (3d Cir.2004). While the Court's consideration of whether Plaintiffs have stated a claim against Defendant MLL is necessarily limited to the allegations in the Complaint, *In re Asbestos Prod. Liab. Litig. (No. VI)*, 822 F.3d 125, 133 (3d Cir. 2016), the Court may consider evidence outside the pleadings for the limited purpose of determining whether to grant Plaintiffs leave to amend the Complaint, *e.g.*, *Jones v. SCO Family of Servs.*, 202 F. Supp. 3d 345, 350 n.4 (S.D.N.Y. 2016) (considering evidence outside the pleadings for limited purpose of whether to grant leave to amend); *Lauter v. Anoufrieva*, 642 F. Supp. 2d 106, 1078 (C.D. Cal. 2009) ("A court may consider factual allegations outside of the complaint in determining whether to grant leave to amend.").

Relying on their evidentiary submissions, Plaintiffs argue that MLL should be considered a submitter because it: (i) appointed MPI as a U.S. agent for Drug Master File ("DMF") No. 34227;

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[22] Plaintiffs identify authority wherein other plaintiffs' claims survive a Rule 12(b)(6) motion to dismiss with allegations that appear as threadbare and conclusory as the allegations at issue here. *See, e.g.*, *Warner Chilcott Co., LLC v. Mylan Pharms., Inc.*, 2017 WL 603309, at *4 (E.D. Tex. Jan. 19, 2017) (recommending denial of motion to dismiss where complaint alleged that defendants are "agents of each other," "work in active concert either directly or through one or more of their wholly owned subsidiaries," and collectively "prepared" the ANDA at issue). To the extent those decisions may conflict with the conclusion here, they are non-binding and not persuasive.

(ii) provides quality assurance and testing of the final drug substance and may manufacture the drug; and (iii) communicated with the FDA New Jersey Division regarding inspections of the facilities for manufacturing and testing of plecanatide in connection with ANDA No. 215686.

First, Plaintiffs assert that MLL should be considered a submitter because it appointed MPI as a U.S. agent for DMF No. 34227 and paid user fees in association with the DMF (Opp. at 8–9.) As courts in this district and elsewhere have recognized, the preparation of a DMF relied on by an ANDA filer is does not transform an entity into a submitter for purposes of Section 271(e)(2). *See, e.g.*, *SmithKline Beecham Corp. v. Geneva Pharm., Inc.,* 287 F. Supp. 2d 576, 584 (E.D. Pa. 2002); *Smithkline Beecham Corp. v. Pentech Pharm., Inc.,* 2001 WL 184804, at *2 (N.D. Ill. Feb. 20, 2001) ("There is no reference in section 271(e)(2)(A) to suppliers of ingredients of generic drug products or preparers of DMFs relied on by ANDA filers. Section 271(e)(2)(A) unambiguously refers only to persons who submit ANDAs.").

Second, Plaintiffs contend that MLL should be considered a submitter because it has taken certain steps with respect to the manufacturing, packaging, labeling, release, and stability testing of plecanatide. (Opp. at 8–10.) This, in conjunction with Defendants' statements about their collective access to MLL's products, evidences MLL's participation in the preparation of the ANDA, according to Plaintiffs. (*Id.*) It does no such thing. As the Federal Circuit emphasized, "it is the *submission* that infringes," not an act "merely 'related to' [the submission] in some broader sense." *Celgene*, 17 F.4th at 1121 (citing *Valeant*, 978 F.3d at 1384 n.8).

Third, Plaintiffs contend that MLL should be considered a submitter because it communicated with the New Jersey Division of the FDA regarding the FDA's inspections of MLL's facilities in connection with manufacturing and testing plecanatide for ANDA No. 215686. Specifically, Plaintiffs direct the Court's attention to two letters: (i) a December 12, 2018 letter

from the FDA's Office of Pharmaceutical Quality Operations, located in New Jersey, to an MLL representative in India and concerning MLL's API manufacturing facilities in India; and (ii) an August 20, 2020 "warning letter" "summarizing significant deviations from current good manufacturing practice (CGMP) for active pharmaceutical ingredients (API)" at those facilities.[23] While these communications may be "'related to' [the submission] in some broader sense," Plaintiffs fail to explain how these are "*part of*" the submission. *Celgene*, 17 F.4th at 1121.

Because any amendment to the Complaint would be futile as to MLL and Agila, the Court will dismiss Plaintiffs' claims against them with prejudice.

C. Motion to Dismiss the Declaratory Judgment Counts for Failure to State a Claim and Lack of Subject Matter Jurisdiction Against All Defendants.

Defendants move to dismiss the Declaratory Judgment Counts for failure to allege any cognizable act of infringement and failure to establish this Court's subject matter jurisdiction. The Declaratory Judgment Act (the "DJA") requires that a "case of actual controversy" exist between the parties before a federal court may exercise jurisdiction. 28 U.S.C. § 2201(a). A court has subject matter jurisdiction over a declaratory judgment action only if the "facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (internal quotation marks and citation omitted). A case or controversy must be "based on a *real* and *immediate* injury or threat of future injury that is *caused by the defendant*[]—an objective standard that cannot be met by a purely subjective or speculative fear of future harm." *Prasco, LLC v. Medicis Pharm.*

[23] While the Court will accept, for argument's sake, Plaintiffs' representation that the August 20, 2020 warning letter was "issued by the FDA New Jersey Division," this fact is not self-evident from the exhibit which Plaintiffs offer for the proposition. (Deni Decl., Ex. 28.) Instead, the warning letter bears a notation indicating that its "issuing office" is located in Maryland. (*Id.*)

Corp., 537 F.3d 1329, 1339 (Fed. Cir. 2008).[24]

Within the patent context, a patentee may seek a declaration that a person will infringe a patent in the future. *See Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1571 (Fed. Cir. 1997); *Lang v. Pacific Marine & Supply Co.,* 895 F.2d 761, 763 (Fed. Cir. 1990). "In the context of a § 271(e)(2) infringement action, where the court is engaged a in a forward-looking analysis of what defendants will do upon ANDA approval, defendants' declared intent is sufficient to make the controversy real and immediate." *Cephalon Inc. v. Watson Pharms., Inc.*, 629 F. Supp. 2d 338, 351 (D. Del. 2009). Yet, the possibility of future infringement lacks sufficient immediacy where FDA approval for the infringing product is "years away." *See Telectronics Pacing Sys., Inc. v. Venritex, Inc.*, 982 F.2d 1520, 1527 (Fed. Cir. 1992); *see also Texas v. United States*, 523 U.S. 296, 300 (1998) ("A claim is not ripe for adjudication if it rests upon contingent future events, that may not occur as anticipated, or indeed may not occur at all."); *Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274, 1277 (Fed. Cir. 2014) ("The immediacy requirement is not concerned in the abstract with the amount of time that will occur between the filing of the declaratory judgment action and the liability-creating event.").

Whether Plaintiffs' claims suffice as an actual controversy under the DJA, the Court in its discretion declines to exercise jurisdiction. Under the DJA, courts "*may* declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201(a) (emphasis added). The statute "confers a 'unique and substantial discretion' on federal courts to determine whether to declare litigants' rights." *Reifer v. Westport Ins. Corp.*, 751 F.3d 129, 139 (3d Cir. 2014) (quoting *Wilton v. Seven Falls Co.*, 515

[24] The requirement of a substantial controversy under the DJA "is the same as an Article III case or controversy." *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.,* 482 F.3d 1330, 1338 (Fed. Cir. 2007) (citing *Aetna Life Ins. Co. v. Haworth,* 300 U.S. 227, 239–41 (1937)).

U.S. 277, 288 (1995). While the Third Circuit has established a number of non-exhaustive factors for district courts to consider when determining whether to exercise jurisdiction under the DJA, the requirement is that courts exercise "sound and reasoned" discretion. *Id.* at 146.[25]

Any relief available to Plaintiffs because of their declaratory judgment claims is duplicative of that available to them pursuant to the Hatch-Waxman Act: Namely, an order which would delay FDA approval of the ANDA until Plaintiffs' patents expire. Adjudication of the declaratory judgment claims "would require the parties to litigate the same issues as under [Plaintiffs'] Hatch-Waxman Act claims" and "will not 'serve a useful purpose in clarifying and settling the legal relations' nor 'terminate and afford relief from . . . uncertainty, insecurity, and controversy.'" *See Noven Therapeutics, LLC v. Actavis Labs. FL, Inc.,* 2015 WL 9918412, at *2 (D.N.J. Feb. 20, 2015); *Apicore US LLC v. Beloteca, Inc.*, 2019 WL 1746079, at *8 (E.D. Tex. Apr. 18, 2019) ("Since Plaintiffs . . . already have an express statutory remedy for patent infringement, they should not be given an additional one in the form of a declaratory action for patent infringement."). If Plaintiffs successfully prosecute their claims for patent infringement, the law already provides an adequate remedy to Plaintiffs without the DJA.

Furthermore, the clear import of the *TC Heartland*, *Valeant*, and *Celgene* decisions is to insert a level of certainty in the determination of venue without turning it into extraordinary game of collateral litigation to select the forum or judge that litigants want. Adjudicating Plaintiffs' claims for declaratory judgment would effectively allow patentees an end-run around these

[25] These factors include: (1) the likelihood that a federal court declaration will resolve the uncertainty of obligation which gave rise to the controversy; (2) the convenience of the parties; (3) the public interest in settlement of the uncertainty of obligation; (4) the availability and relative convenience of other remedies; (5) a general policy of restraint when the same issues are pending in a state court; (6) avoidance of duplicative litigation; (7) prevention of the use of the declaratory action as a method of procedural fencing or as a means to provide another forum in a race for res judicata. *Id.*

limitations on venue while maintaining some of the benefits allowed them via the Hatch-Waxman Act. *Cf. Apicore US LLC*, 2019 WL 1746079, at *7 (finding plaintiffs "cannot avoid the requirements of § 1400(b) by wrapping its patent infringement claim inside the blanket of a declaratory judgment action"); *Bristol-Myers Squibb Co.*, 2018 WL 5109836, at *5 (declining to adjudicate plaintiffs' claims for declaratory relief where they already had "the benefit of the automatic 30-month stay of FDA approval of [the] ANDA, a benefit to which [p]laintiffs would not have been entitled to if their cause of action were anything other than a claim for patent infringement."). As this case is incontestably a "civil action for patent infringement," venue is governed solely and exclusively by § 1400(b).

D. The Action Will Be Transferred to the Northern District of West Virginia Pursuant to 28 U.S.C. § 1404(a)

If a court determines that venue is improper, the court "shall dismiss, or if it be in the interest of justice, transfer such case to any district or division in which it could have been brought." 28 U.S.C. § 1406(a). "Dismissal is considered to be a harsh remedy . . . and transfer of venue to another district in which the action could originally have been brought, is the preferred remedy." *Best Med. Int'l, Inc. v. Elekta AB*, 2019 WL 3304686, at *2 (D. Del. July 23, 2019) (internal quotation marks and citation omitted).

Although Plaintiffs do not address in their papers whether the claims should be transferred to the Northern District of West Virginia in lieu of dismissal, Defendants concede that the Plaintiffs could have pursued a patent infringement suit against MPI there.[26] The Court concurs and will

[26] Plaintiffs contend that "Defendants' presence in West Virginia effectively ended as a result of the Viatris merger," and in support of this Plaintiffs submit several newspaper articles reporting on the closure of a Mylan Pharmaceuticals plant in Morgantown, West Virginia. (Opp. at 6-7 (citing Deni Decl. Exs. 20-21).) However, MPI remains incorporated in West Virginia, the actual submission of the ANDA occurred in West Virginia, and Defendants aver that MPI "continues its operations at multiple facilities" in Morgantown. (Meckstroth Decl. at ¶¶ 6, 35; Supp. Meckstroth Decl. ¶ 3.) Even construing all factual

transfer the Infringement Counts as to MPI to the Northern District of West Virginia in the interest of justice. The interest of justice does not, however, require that the Court transfer to any other District the Infringement Counts against Defendants Viatris, Mylan Inc., and Mylan API: Doing so would be an exercise in futility. *Supra* Sections II.A.2, II.A.4. Accordingly, these claims will be dismissed.

III. Conclusion

For the reasons set forth above, Defendants' motion will be granted in part and Plaintiffs' cross-motion will be denied.[27] Counts III, IV, V and VI are dismissed without prejudice as to all Defendants, the Declaratory Judgment Counts are dismissed with prejudice as to all Defendants, and the Infringement Counts will be dismissed with prejudice as to Mylan Inc., Mylan API, Viatris, MLL and Agila. In the interest of justice, the action and all remaining claims—namely, the Infringement Counts as to MPI—will be transferred to the Northern District of West Virginia as the proper venue. An appropriate Order will issue.

/s/ Stanley R. Chesler
HON. STANLEY R. CHESLER
United States District Judge

Dated: March 8, 2022

disputes in Plaintiffs' favor, there is no doubt that venue is proper in the Northern District of West Virginia under Section 1400(b).

[27] Because all claims against MLL are dismissed as a result of the Court's prior analyses, the Court declines to consider Defendants' motion, pursuant to Fed. R. Civ. P. 12(b)(2), to dismiss MLL for lack of personal jurisdiction.